UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

GHISELLE WATSON	CIVIL ACTION
v.	NO. 13-212
BAYER HEALTHCARE PHARMACEUTICALS, INC.	SECTION "F"

ORDER AND REASONS

Before the Court is the defendant's motion to dismiss. For the reasons that follow, the motion is GRANTED.

Background

This products liability lawsuit concerns an intrauterine contraceptive system marketed as Mirena®, which is manufactured and distributed by Bayer Healthcare Pharmaceuticals, Inc.

Mirena® is an intrauterine device that is made from flexible plastic and inserted in a patient's uterus by a health care provider during an office visit. Once inserted, the system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Although it is not known exactly how Mirena® works, it is believed that Mirena® thickens cervical mucus, thins the uterine lining, inhibits sperm movement, and reduces sperm survival to prevent pregnancy.

Bayer Healthcare Pharmaceuticals, Inc., develops, designs, licenses, manufactures, distributes, and markets Mirena®. Today, an estimated 2 million women in the United States and 15 million

women worldwide use Mirena®. Mirena® is designed to be placed in the patient's uterus within seven days of the first day of menstruation. The Food and Drug Administration approved Bayer's new drug application in 2000 for continued intrauterine use for a term of five years. If the patient wants to continue using Mirena after five years, the old system must be removed and a new one inserted.

Mirena® labeling recommends that it be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after its use. Its label does not warn about spontaneous migration of the device; it states only that migration may occur if the uterus is perforated during insertion.

Notwithstanding the increasing number of MedWatch Adverse Event reports related to embedment of and perforation through the uterine lining or migration of the device through the uterine lining after the period of insertion, Bayer has not altered the product's packaging or labeling. In fact, Bayer has a history of overstating the efficacy of Mirena®, while understating its safety concerns.

In March 2009, the Department of Health and Human Service's Division of Drug Marketing, Advertising and Communications (DDMAC) warned that Bayer's advertising materials for Mirena® constituted misbranding in violation of the FDA. Specifically, the DDMAC stated that Bayer failed to communicate any risk information,

inadequately communicated Mirena®'s indications, and overstated its efficacy in Bayer-sponsored internet search engines. The DDMAC requested Bayer immediately cease dissemination of the advertising materials.

Months later, in December 2009, the DDMAC again contacted Bayer regarding a Bayer-directed advertising program entitled "Mirena® Simple Style Statements Program." This program -- presented in a consumer's home by a representative from "Mom Central", a social networking site, and a nurse practitioner, in partnership with Bayer -- consisted of a live presentation designed for "busy moms". The program materials represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. But DDMAC determined that these claims were unsubstantiated, noting to the contrary that Mirena®'s packaging itself states that at least 5% of clinical trial patients reported a decreased libido after use. The program also represented that Mirena® can help patients "look and feel great." But DDMAC determined that these claims were also unsubstantiated, pointing out that the side effects of Mirena® include weight gain, acne, and breast pain or tenderness. DDMAC also concluded that the portion of the program relating to Mirena® risks omitted information about serious conditions such as the risk of infection and miscarriage. As a result, DDMAC again ordered Bayer stop using advertising that violated the FDA.

Ghiselle Watson is a 43-year old woman. She began using Mirena® when her doctor inserted the device in 2007. Ms. Watson's doctor placed the Mirena® system in Ms. Watson's uterus with no difficulties, nor were there any no indications that the device perforated her uterus.

From 2007 until 2012, Ms. Watson visited her doctors for follow-up appointments, at which time it was noted that the Mirena® was in good placement. However, in 2012, Ms. Watson began to experience abdominal pain; she became concerned that the intrauterine device was causing that pain. Tests completed by Ms. Watson's doctor revealed that, in fact, the Mirena® system had embedded in her uterus. Because the device had shifted, Ms. Watson underwent surgery under anesthesia to remove the Mirena® device.

On February 5, 2013 Ms. Watson sued Bayer Healthcare Pharmaceuticals, Inc. in this Court, invoking the Court's diversity jurisdiction. She presents several state law claims against Bayer, including claims that Mirena® was defective pursuant to the Louisiana Products Liability Act; she also alleges negligence, failure to warn, breach of implied warranty, breach of express warranty,negligent misrepresentation, fraudulent misrepresentation, and concealment. Ms. Watson seeks an award of actual damages incurred, including past and future reasonable and necessary medical expenses and rehabilitation expenses; past and future physical pain and suffering; past and future mental anguish; past

and future physical disfigurement; past and future physical impairment; past and future lost earnings and lost earning capacity.

Defendant Bayer Healthcare Pharmaceuticals now seeks to dismiss Ms. Watson's claims for failure to state a claim upon which relief can be granted.

I.

Rule 12(b)(6) of the Federal Rules of Civil Procedure allows a party to move for dismissal of a complaint for failure to state a claim upon which relief can be granted. Such a motion is rarely granted because it is viewed with disfavor. See Lowrey v. Tex. A & M Univ. Sys., 117 F.3d 242, 247 (5th Cir. 1997) (quoting Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc., 677 F.2d 1045, 1050 (5th Cir. 1982)).

Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009)(citing Fed.R.Civ.P. 8). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Id. at 678 (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

Thus, in considering a Rule 12(b)(6) motion, the Court "accepts 'all well-pleaded facts as true, viewing them in the light

most favorable to the plaintiff.'" See Martin K. Eby Constr. Co. v. Dall. Area Rapid Transit, 369 F.3d 464 (5th Cir. 2004) (quoting Jones v. Greninger, 188 F.3d 322, 324 (5th Cir. 1999)). But, in deciding whether dismissal is warranted, the Court will not accept conclusory allegations in the complaint as true. Kaiser, 677 F.2d at 1050. Indeed, the Court must first identify allegations that are conclusory and, thus, not entitled to the assumption of truth. Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009). A corollary: legal conclusions "must be supported by factual allegations." Id. at 678. Assuming the veracity of the well-pleaded factual allegations, the Court must then determine "whether they plausibly give rise to an entitlement to relief." Id. at 679.

"'To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" Gonzalez v. Kay, 577 F.3d 600, 603 (5th Cir. 2009)(quoting Iqbal, 556 U.S. at 678)(internal quotation marks omitted). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citations and footnote omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 ("The

plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully."). This is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. at 679. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. at 678 (internal quotations omitted) (citing Twombly, 550 U.S. at 557). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief'", thus, "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (alteration in original) (citation omitted).

Finally, "[w]hen reviewing a motion to dismiss, a district court 'must consider the complaint in its entirety, as well as other sources ordinarily examined when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011)(quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007)).

II.

A.

The Louisiana Products Liability Act (LPLA) provides the exclusive remedy for products liability claims, or harm caused by

a manufacturer's product. LA REV. STAT. ANN. § 9:2800.52; Demahy v. Schwarz Pharm, Inc., 702 F.3d 177, 182 (5th Cir. 2012); Jefferson v. Lead Indus. Ass'n, Inc., 106 F. 3d 1245, 1250-51 (5th Cir. 1997). This means that "[a] plaintiff may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability not set forth in the LPLA." La.R.S. § 9:2800.52. Moreover, even though an action under the LPLA is predicated on principles of strict liability, negligence, or warranty, these theories are not available as independent theories of recovery against the manufacturer. Stahl v. Novartis Pharma. Corp., 283 F.3d 254, 261 (5th Cir. 2002).

Ms. Watson's claims against Bayer arise out of her use of its product, Mirena®. Accordingly, the LPLA establishes Ms. Watson's sole theories of recovery against Bayer, and any claims pleaded beyond the scope of her exclusive remedy under the LPLA must be dismissed. Bayer contends that, of the eight claims asserted in her complaint, only the first one is brought pursuant to the LPLA and that, therefore, the other seven claims are contrary to the exclusive remedy provision and must be dismissed. The Court agrees.

Ms. Watson's claims that are not brought pursuant to the LPLA, which include those claims asserting negligence, failure to warn, breach of implied warranty, breach of express warranty, negligent misrepresentation, fraudulent misrepresentation and

concealment, must be dismissed.[1]

B.

The Court now considers whether Ms. Watson has alleged a right to relief under the LPLA that is plausible on its face. The parties dispute whether the facts as alleged comply with the pleading standards under Federal Rule of Civil Procedure 8(2)(a).

Under the LPLA, a plaintiff must prove that (1) the defendant is the manufacturer of the product; (2) her injury or damage was proximately caused by a characteristic of the product; (3) this characteristic made the product "unreasonably dangerous"; and (4) the plaintiff's damage arose from a reasonably anticipated use of the product. Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 261 (5th Cir. 2002). A plaintiff may prove that a product is "unreasonably dangerous" only by establishing that it is so: (1) in construction or composition; (2) in design; (3) due to inadequate warning; or (4) due to nonconformity to an express warranty. Id.; La.R.S. § 9:2800.54(B)(1-4). Bayer insists that the plaintiff has failed to state a claim under any of these theories. The Court agrees.

1. Defective Construction or Composition

A defective construction claim provides a remedy for harm caused by a product defect "due to a mistake in the manufacturing

[1]The Court notes that the plaintiff does not appear to oppose this outcome, given that she fails to address the exclusive remedy provision issue in her opposition papers.

process." Stahl, 283 F.3d at 263. In presenting a defective construction or composition theory of recovery under the LPLA, the plaintiff must prove that, at the time the product left the manufacturer's control, it deviated materially from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer. La.R.S. § 9:2800.55.

Bayer contends that the plaintiff's defective construction claim fails to allege facts that, if proven, would demonstrate a mistake in the manufacturing process. The Court agrees.

Ms. Watson claims that Mirena®'s "condition when sold was the proximate cause of the injuries." But she fails to allege facts about the "condition", or suggest how Mirena® deviated from its intended design. She also fails to allege facts explaining how the unknown manufacturing defect caused her alleged injuries. Absent factual allegations addressing how the Mirena® deviated from Bayer's normal production standards, the plaintiff fails to meet the plausibility standard.

2. Defective Design

A product's design is unreasonably dangerous only if the plaintiff demonstrates that, at the time the product left the manufacturer's control, "'[t]here existed an alternative design for the product that was capable of preventing the claimant's damage' and that the danger of the damage outweighed the burden on the

manufacturer of adopting the alternative design." Jacobsen v. Wyeth, LLC, No. 10-823, 2012 WL 3575293, at *6 (E.D. La. Aug. 20, 2012)(quoting La.R.S. § 9:2800.56). The LPLA "does not allow a fact finder to presume an unreasonably dangerous design solely from the fact that injury occurred." McCarthy v. Danek Medical, Inc., 65 F. Supp. 2d 410, 412 (E.D. La. 1999).

In her complaint, Ms. Watson alleges that Mirena had an "inadequate design", "unreasonably dangerous design defects," and an "unstable and defective design" and that "[t]here are contraceptives on the market with safer alternative designs." Bayer contends that these allegations fail to satisfy federal pleading standards. The Court agrees. The plaintiff has failed to allege how Mirena®'s design is defective, what aspect of Mirena®'s design caused her injuries, or how the defective design relates to her specific injuries. “[A] plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’”, thus, “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Twombly, 550 U.S. at 555 (alteration in original) (citation omitted).

3. Inadequate Warning

To establish an inadequate warning claim regarding a prescription drug, a plaintiff must show that: (1) the defendant failed to warn her doctor of a risk associated with the product that was otherwise unknown to the doctor; and (2) the failure to

warn the doctor was both a cause in fact and the proximate cause of the plaintiff's injury. Stahl, 283 F.2d at 265-66.

Ms. Watson alleges in her complaint that Mirena® is defective because its labeling failed to warn of the "risk of migration of the product post-insertion, development of endometriosis resulting from uterine perforation, or the possibility that device complication may necessitate hysterectomy." However, as Bayer points out, the plaintiff fails to allege that she actually experienced any of these particular complications. She simply alleges that she was injured when Mirena® embedded in her uterus. She fails to allege facts suggesting how Bayer's allegedly inadequate warning caused her specific injury.[2] Ms. Watson's failure to allege facts showing a causal connection between her injury and Mirena®'s warning renders her inadequate warning claim implausible. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 ("The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer

[2]It is unclear under the facts alleged that the Mirena® device actually migrated, causing it to embed in her uterus and cause her injury. Thus, it is unclear how Bayer's failure to warn about the risk of migration proximately caused the Mirena® to embed in Ms. Watson's uterus.

possibility that a defendant has acted unlawfully.").[3]

C.

Finally, Bayer also seeks dismissal of the plaintiff's punitive damages claim. The plaintiff concedes that punitive damages are not available under the LPLA. The plaintiff's punitive damages claim is also dismissed.

Accordingly, the defendant's motion to dismiss is GRANTED. However, if the plaintiff in good faith believes that she can allege facts curing the defects of her LPLA claim, she must seek leave to file an amended complaint within fourteen days.

New Orleans, Louisiana, April 11, 2013

MARTIN L. C. FELDMAN
UNITED STATES DISTRICT JUDGE

[3]Bayer finally contends that the complaint does not purport to assert a theory of recovery based on nonconformity with an express warranty. The Court agrees. Because no such theory was ever asserted, the abstract plausibility of such a claim cannot be considered.